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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,052	06/29/2001	Frank J. Bunick	MCP-281	9476

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/896,052	BUNICK ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/25/09 has been entered.

Claim Rejections - 35 USC § 103

Claims 1-6 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly et al. US 6,432,441, in view of Puglia et al. US 4,271,142 and Mackles US 4,260,596.

Bealin-Kelly teaches a throat drop composition comprising an aqueous filled center in the form of paste or gel (abstract; and column 2, lines 21-27). The gel or paste center filled comprising active agents having particle size of from about 1 μm to about 100 μm (column 3, lines 14-23). Active agents include analgesic (column 2, lines 28-34). The center filled is coated with a shell composed of chewing gum or hard or soft candy (column 4, lines 23-43).

Bealin-Kelly does not expressly teach the composition of the gel or past center filled.

Puglia teaches an aqueous gel center filled composition comprising thickener such as gelatin and pectin (column 3, lines 60 through column 4, lines 1-2; and examples).

Thus, it would have been obvious to one of ordinary skill in the art to modify the center filled composition of Bealin-Kelly to include gelatin or pectin in view of the teachings of Puglia. This is because Puglia teaches the use of thickener in a gel or paste composition is well known in the art, because Puglia teaches that gelatin or pectin is a well known center filled component useful in the art, and Bealin-Kelly teaches the desirability for preparing a gel or paste center filled composition.

Bealin-Kelly further does not teach the claimed ratio between the active agent to the shell. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the present case, applicant has not shown that such ratio result in any unexpected and/or unusual result. Therefore, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine suitable amount of active agent depends in the desirability of use.

Bealin-Kelly further does not expressly teach the claimed thickness of the edible shell.

Mackles teaches an edible unit dosage form comprising a liquid or gel center containing an active agent, and an outer edible shell having thickness generally in the range of about 0.5 to about 3.0 mm (abstract; Figs.; and column 2, lines 57-61). Thus, it would have been obvious to one of ordinary skill in the art to optimize the edible shell of Bealin-Kelly to have the thickness that falls within the claimed range. This is because Mackles teaches edible shell having the claimed thickness is useful for coating aqueous filled center, because Bealin-Kelly teaches an aqueous filled center, and because Bealin-Kelly teaches the desirability for preparing an edible coating such as chew gum or hard or soft candy.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee US 6,0606,078, in view of Mehta US 4,800,087, Siva et al. US 4,753,790, Mackles US 4,260,596, and Buehler et al. US 6,432,442.

Lee teaches a chewable pharmaceutical dosage form comprising of a core containing an active ingredient, and an outer layer (See Figure 2). The dosage form demonstrates improved organoleptic properties when chewed, such as taste (See column 1, lines 47-52). The core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin (See column 2, lines 29-33). In addition, gelatin may be used in either the core or outer layer to maintain hardness and extension property in the dosage form (See column 2, lines 59-61). The outer layer may take a variety of forms, including hard candy (See column 2, lines 34-42). Acetaminophen is listed as a possible active ingredient in the core (See Column 2, Lines 9-18). In

addition, Lee contains what the examiner will interpret as an enabling disclosure of a dosage form with a unitary core (See Figure 2; and MPEP § 2125). The disclosed invention has the advantage of having an improved chewing property, which the examiner broadly interprets as having a texture masking property, in addition to having a taste masking property (See Column 3, Lines 53-58).

The Lee patent does not teach the use of ibuprofen in the disclosed dosage form, nor does it expressly disclose particles sizes for the active agent. The Lee patent does not teach the use of an outer shell that is about 20% to about 50% of the total weight of the dosage form, nor does it teach that such an outer shell has a thickness of about 500 to 3000 microns.

Mehta teaches a chewable, taste-masked pharmaceutical dosage form; preferably in the form of a tablet (See Column 1, Lines 6-28). The components of this dosage form consist of taste-masked microcapsules, which may then be prepared as chewable tablets. The microcapsules themselves comprise a polymeric coating that masks the taste of the active ingredient, and a pharmaceutical core (See Column 4, Lines 4-12; and Examples 1 and 2). In one embodiment, the polymeric coating may be composed of a low-temperature film-forming polymer that produces a film at temperatures below 25°C., in order to produce microcapsules ranging in size from 10 microns to 1.5 mm in diameter (See Column 5, Lines 49-66). Acetaminophen and ibuprofen are listed among suitable drugs for use in the reference (See Column 7, Lines 31-48; and Claims 11 and 12). Diluents acceptable for use in the microcapsule core include gelatin (See column 7, line 59 to column 8, line 12). In the given examples, the

preferred size of the uncoated acetaminophen particles used lies in the range of 150 to 300 microns (See Column 10, Lines 45-47). The reference also teaches that the coated pharmaceutical cores may then be encapsulated in a hard gelatin capsule or further coated with candy (See Column 9, Lines 35-40).

The Silva *et al.* patent discloses a coated comestible having a hard outer shell (See Abstract). The dosage form comprises a core that is coated with the shell, where the core can be in various forms, such as gums, candies, jellies, and pills or tablets used for medicinal purposes (See Column 3, Lines 20-32). In the examples provided, the final coated products have an outer shell in a quantity that ranges from approximately 20% to 40% by weight of the product (See Examples I to V; and Tables 5, 9, 13, 17 and 18).

The Mackles patent teaches an edible unit dosage form having an outer shell and a liquid or gel center containing an active agent (See Abstract; and Figures). Although the thickness of the shell may vary, it is generally in the range of about 0.5 to about 3.0 mm (See Column 2, Lines 57-61).

It would be obvious to one of ordinary skill in the art to combine the teachings of Lee, Mehta, Silva *et al.*, and Mackles into the objects of the instant application. Both the Lee and Mehta patents deal with the administrations of drugs in pharmaceutical compositions with improved organoleptic properties. Therefore, one of ordinary skill would be motivated to incorporate the microcapsules disclosed in Mehta into the dosage form of Lee in order to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked without an undue delay on the release of the

drug. As Mehta states that the disclosed compositions may be incorporated into chewable tablets, in the view of the examiner, this disclosure provides sufficient guidance to one of ordinary skill in the art to incorporate them into the chewable dosage form taught in Lee. As such, it is the position of the examiner that one of ordinary skill in the art could combine the disclosures of the prior art with a reasonable expectation of success.

One of ordinary skill in the art would be motivated to incorporate the teachings of Silva *et al.* and Mackles into the disclosure of Lee, as Silva *et al.* and Mackles provide specific guidance as to how one of ordinary skill in the art may construct an outer shell for an edible dosage form. Such guidance would therefore lead one of ordinary skill in the art to provide are more carefully constructed outer shell that having improved organoleptic properties for the purpose of increasing patient acceptance and compliance. As Lee, Silva *et al.* and Mackles provide for dosage forms having a hard outer shell and softer core, they are analogous. Therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together.

The adjustment and optimization of parameters such as hardness of the soft core and the weight ratio of active agent particles are considered by the examiner to be well within the purview of one of ordinary skill in the art. Therefore, claim limitations drawn to such features are not considered by the examiner to impart a patentable quality unto the instantly claimed invention.

Lee further does not teach the claimed aqueous soft core which comprises water and hydrocolloid.

Buehler teaches a chewable product comprising gelatin matrix and hydrocolloid such as pectin (abstract; and column 3, lines 1-15). The product further comprises water (column 5, lines 6-23). Thus, it would have been obvious to one of ordinary skill in the art to modify the chewable dosage form of Lee using gelatin and pectin in view of the teachings of Buehler. This is because Buehler teaches the use of hydrocolloid such as pectin in a chewable dosage form is well known in the art, because Lee teaches the use of jelly base chewable product with the desirability for using pectin.

Response to Arguments

Applicant's arguments filed 03/25/09 have been fully considered but they are not persuasive.

Applicant argues that *Bealin-Kelly et al.* states that the vesicles have a number average particle size of from about 1 to about 100 µm. In contrast, Applicants' invention as recited in claim 1, requires that the active agent particles have an average size of greater than about 50 µm. Thus, the fact that the vesicles used in *Bealin-Kelly et al.* have a number average particle size of from about 1 to about 100 µm does not mean that the active agent particles have an average size greater than about 50 µm. As such, claim 1 is patentable over *Bealin-Kelly et al.* Further, neither *Puglia et al.* nor *Mackles* remedy the deficiencies of *Bealin-Kelly et al.*, since neither teach nor suggest active agent particles having an average size greater than about 50 µm.

However, in response to applicant's argument, it is noted that in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); See also *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped). In the present case, the claimed particle size clearly lies inside ranges disclosed by the prior art. Accordingly, the 103(a) rejection over Bealin-Kelly is maintained.

Applicant argues that *Mehta* uses a method where a powdered or granular active agent, and diluent or bulking agent are used to form wet mass utilizing water or a pharmaceutically acceptable solvent. The mixture is subsequently dried, creating a dry pharmaceutical core. See *Mehta*, column 8, lines 29-43. Thus, the pharmaceutical core *of Mehta* is not soft. As such, *Mehta* teaches away from Applicants' claimed invention. *Silva* teaches a coated comestible having a core coated with a hard outer shell. The core can be of various forms, including for example, gums, candies and jellies. Furthermore, coated comestible may be used for medicinal purposes. *Buehler et al.* discloses a chewable product with a gelatin matrix that may include a hydrocolloid and water. Applicants respectfully submit that the proposed combination of *Lee, Mehta,Silva, Mackles*, and *Buehler et al.* is based upon hindsight reconstruction.

Applicants note that the teachings *of Mehta,* teach away from the proposed combination.

In response to applicant's argument with respect to Mehta, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Mehta is cited solely for the teaching of the claimed active agents that can be delivered through chewable dosage form.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615